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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,271	04/14/2004	Shibnath Ghosal	4822-111.1 US	6209

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EXAMINER

HEARD, THOMAS SWEENEY

ART UNIT PAPER NUMBER

1654

DATE MAILED: 08/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/824,271

Applicant(s)

GHOSAL, SHIBNATH

Examiner

Thomas S. Heard

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/5/2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 26-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-19 and 26-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The Applicants Amendments to the claims received on 6/5/2006 is acknowledged. The text of those sections of Title 35 U.S. Code not included in the action can be found in the prior office action. Rejections or objections not addressed in this office action with respect to the previous office action mailed 12/29/2005 are hereby withdrawn.

Claim Rejections - 35 USC § 112

Claims 1-19 and 26-29 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As stated in the previous office action there is not a specific example of a compound comprising a dibenzo-alpha-pyrone that discloses specific chromo-proteins, lipids, and the various functional groups claimed for the dibenzo-alpha-pyrone moiety. The presumed structure example does not share a common core structure, as creatine (and the other functional moieties) can be presumably connected to R³ or R⁸ without any evidence. While having written description for dibenzo-alpha-pyrone identified in the specification tables and/or examples, the specification is void of specific peptides, organic molecules (lipids and chromo-peptides) that qualify for the functional characteristics claimed as the biomolecules. The claimed and disclose molecular

structure is merely a potential structure based on chemical and not structural determination. Lipase reactions "suggested" that lower MW lipids were present and that higher MW proteins, "like B-48" might be present in dibenzo-alpha-pyrone, see pages 23 and 24 of the specification. The "suggestion" that "dibenzo-alpha-pyrone are associated with low/medium weight lipoproteins is also indicative of the molecule not being completely described as to have proper written description. Thus, there is insufficient description of a common core structure that would allow one of skill in the art to practice the invention as claimed. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. Accordingly, it is maintained that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claims 1-19 and 26-29 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition of a fractionated extract of Shilajit, does not reasonably provide enablement for the specific compositions instantly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The natural product Shilajit and Shilajit extracts are well known in the art and are also well known to contain dibenzo-alpha-pyrone, see Ghosal, S, "Shiljit: Its Origin and

Vital Significance", Traditional Medicine, Proceedings of an International Seminar, Nov. 7-9, 1992, Hotel Taj Bengal, Calcutta, India-, pp. 308-319. Since the defined core structure that is correlated with the pharmaceutical function remains largely unsolved, means for determining both is highly unpredictable. The specification has provided an alleged structure, or best guess, of a generic. However, the specification does not provide specific examples of the claimed compounds. Considering the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to synthesize and/or extract and test the compounds that might be correlated to a generic structure and test them in a trial and error basis to determine which ones were active and what the structure is that is correlated to function. It is the examiner's position that one skilled in the art could not practice the invention commensurate in the scope of the claims without undue experimentation.

Claim Rejections - 35 USC § 102

Claims 1-19 and 26-29 stand rejected under 35 U.S.C. 102(b) as being anticipated by Rowland US Patent 5,405,613. Applicants have amended the claims to recite the word 'isolated' to overcome the rejection. '613 disclose the pharmaceutical and nutritional supplement that contains Shilajit or a Shilajit extract that are the source of DCPs. The recitation of isolated with comprising is still Shilajit as Shilajit is rich in DCPs yet comprises a myriad of other composition in addition to those recited in the claims. The extraction process argued against the 102(b) does not overcome the art

rejection as what the Applicant's is claiming is a composition of DCPs isolated from Shilajit and '613 discloses extracts of Shilajit. Therefore, the composition as claimed is anticipated by '613.

Conclusion

No claims are allowed

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

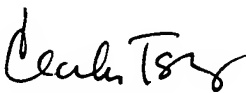
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas S. Heard whose telephone number is (571) 272-2064. The examiner can normally be reached on 9:00 a.m. to 6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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